

REMARKS

Prior to this Response, an Office Action was mailed September 7, 2005.

In the Office Action, regarding the Claims:

Claims 1, 11, and 12 were rejected under 35 U.S.C. § 103(a) as unpatentable over EP 0372127A1 to L'Esperance or US 6,042,594 to Hellenkamp;

Claims 2 and 13 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 4,173,980 to Curtin;

Claims 3-10 and 14-21 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 5,591,174 to Clark, et al;

Claims 3-10 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, and Curtin, in combination with Clark;

Claims 14-21 were rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to further limit method claims 11-13, from which they depend.

In this Response, regarding the Claims, all rejections are respectfully traversed. No amendment made was related to the statutory requirements of patentability unless expressly stated herein. No amendment made was for the purpose of narrowing the scope of any claim, unless Applicant has argued herein that such amendment was made to distinguish over a particular reference or combination of references.

Claims 1-21 are now pending in the present application. Reconsideration is requested. In addition to the above amendments, the Applicant makes the following remarks regarding individual issues:

THE APPLICANT'S TIME TO RESPOND

The last Office Action was mailed on September 7, 2005. The three-month initial deadline for responding without having to pay a penalty fee ended on December 7, 2005. The Applicant hereby encloses a 1-month small entity extension fee. The initial deadline is thus extended to January 7, 2005. In determining whether this document is timely filed, the Patent Office is asked to note the Applicant's Certificate of Mailing in conjunction with 37 C.F.R. § 1.8.

THE SECTION 112, SECOND PARAGRAPH, REJECTION

The Commissioner rejected Claims 14-21 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to further limit method claims 11-13. Specifically, the Commissioner appears to argue that addition of apparatus limitations to further limit method claims is improper. The MPEP and case precedent make clear that process or method claims may merely define the inherent function of a machine or apparatus:

“In view of the decision of the Court of Customs and Patent Appeals in *In re Tarczy-Hornoch*, 397 F.2d 856, 158 U.S.P.Q. 141 (C.C.P.A. 1968), process or method claims are not subject to rejection by Patent and Trademark Office examiners under 35 U.S.C. 112, second paragraph solely on the ground that they define the inherent function of a disclosed machine or process.”

MPEP § 2173.05(v). Although Applicant respectfully traverses the Commissioner's rejection, Applicant proposes amendments below, to clarify the nature of those claims. Applicant views these proposed amendments as for form

only, and not relating to substantive issues of patentability. Specifically, Claims 14-21 have been amended to read:

14. The method of claims 11 or 12, ~~wherein the eye fixation apparatus [further comprising adjustably connecting] a first annular translation guide member adjustably connected to the eye fixation portion wherein the first translation guide member portion can translate laterally in relation to the eye fixation portion [to translate said first guide member laterally in relation to the eye fixation portion]~~.

15. The method of claim 14, ~~wherein the first translation guide member is provided with a first translation rod and a first adjustment knob for translating the first translation guide member [adjusted using a first translation rod and a first adjustment knob]~~.

16. The method of claim 13, ~~wherein the eye fixation apparatus is further provided with a docking screw screwed through the first translation guide member for tightening the first translation guide member against objects inserted into the cylindrical space formed by the first annular translation guide member. [further comprising tightening the first translation guide member against objects inserted into the cylindrical space formed by the first annular translation guide member with a docking screw threaded through the first translation guide member]~~.

17. The method of claim 14, ~~wherein the eye fixation apparatus is further provided with a docking screw screwed through the first translation guide member for tightening the first translation guide member against objects inserted into the cylindrical space formed by the first annular translation guide member. [further comprising tightening the first translation guide member against objects inserted into the cylindrical space formed by the first annular translation guide member with a docking screw threaded through the first translation guide member]~~.

18. The method of claim 14, ~~wherein the eye fixation apparatus is further provided with a second translation guide member adjustably connected to the first translation guide member, wherein the second translation guide member can translate laterally in relation to the first translation guide member in a direction not parallel to the translation of the first translation guide member [further comprising adjustably connecting a second translation guide member to the first translation guide member to translate said second guide member in a direction non-parallel to the first guide member]~~.

19. The method of claim 18, ~~wherein the second translation guide member is provided with a second translation rod and an adjustment knob~~

~~for adjusting the second translation guide member [adjusted using a second translation rod and a second adjustment knob].~~

20. The method of claim 18, ~~wherein the eye fixation apparatus is further provided with a docking screw screwed through the second translation guide member for tightening the second translation guide member against objects inserted into the cylindrical space formed by the annular second translation guide member. [further comprising tightening the second translation guide member against objects inserted into the cylindrical space formed by the second annular translation guide member with a docking screw threaded through the second translation guide member].~~

21. The method of claim 19, ~~wherein the eye fixation apparatus is further provided with a docking screw screwed through the second translation guide member for tightening the second translation guide member against objects inserted into the cylindrical space formed by the annular second translation guide member. [further comprising tightening the second translation guide member against objects inserted into the cylindrical space formed by the second annular translation guide member with a docking screw threaded through the second translation guide member].~~

While Applicant believes claims 14-21 were not invalid as written, it is believed that the amendments make clarify the added method limitations of these dependent claims. These amendments are supported in the Specification. Accordingly, the rejection should be withdrawn.

THE SECTION 103(A) OBVIOUSNESS REJECTIONS

A. Claims 1, 11, and 12

The Commissioner rejected Claims 1, 11, and 12 under 35 U.S.C. § 103(a) as being unpatentable over L'Esperance or Hellenkamp. Claims 2 and 13 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 4,173,980 to Curtin. Claims 3-10 and 14-21 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp, in combination with US 5,591,174 to Clark, et al. Claims 3-10 were rejected under

§ 103(a) as unpatentable over L'Esperance or Hellenkamp, and Curtin, in combination with Clark.

In the case of a Section 103(a) obviousness rejection, it is the Patent Office's initial burden to put forward a prima facie case, without which the Applicant is not required to submit evidence of nonobviousness. MPEP 2142, 2143; In re Mayne, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997). The prima facie case requires:

"First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure."

MPEP 2143. Section 103 requires analysis of a claimed invention as a whole:

"It is true that [the claimed invention] consists of a combination of old elements so arranged as to perform certain related functions. It is immaterial to the issue, however, that all of the elements were old in other contexts. What must be found obvious to defeat the patent is the claimed combination. ... Focusing on the obviousness of substitutions and differences, instead of on the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness."

The Gillette Co. v. S.C. Johnson & Son Inc., 16 USPQ2d 1923 (Fed. Cir. 1990).

The legal determination under Section 103 is whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art at the time the invention was made. In re O'Farrell, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). The foundational facts for the prima facie case of obviousness are: (1) the scope and content of the prior art; (2) the difference between the prior

art and the claimed invention; and (3) the level of ordinary skill in the art. Graham v. John Deere Co., 383 U.S. at 17-18; Miles Lab., Inc. v. Shandon Inc., 27 USPQ2d 1123, 1128 (Fed. Cir. 1993). Moreover, objective indicia such as commercial success and long felt need are relevant to the determination of obviousness. Stratoflex, Inc. v. Aeroquip Corp., 218 USPQ 231, 236 (Fed. Cir. 1983). Thus, each obviousness determination rests on its own facts. In re Durden, 226 USPQ 359, 361 (Fed. Cir. 1985).

Moreover, "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 230 USPQ 416 (Fed. Cir. 1986).

Here, one skilled in the art reading L'Esperance (EP '127) would not be motivated to discover or build Applicant's invention. As such L'Esperance neither renders unpatentable, nor is analogous to, Applicant's invention. L'Esperance teaches an eye-retaining device consisting of a hollow annulus with a convergent axial end wall made from air-permeable material shaped to engage the cornea. The porous air-permeable end wall of L'Esperance is easily clogged by mucous from the corneal surface with at least two negative results, both of which are resolved by Applicant's invention. First, the end wall is virtually impossible to completely clean and would have to be replaced for each surgical procedure. Hellenkamp discusses the importance and difficulty of cleaning conventional vacuum rings, and the device disclosed in L'Esperance would exacerbate those

difficulties. Second, the clogged pores of the end walls result in a flat surface which creates inherent suction when placed in contact with the corneal surface, both due to vacuum created by displacement of fluid on the corneal surface and surface tension of the fluid itself. This inherent suction makes it difficult or impossible to break vacuum without damaging the cornea, including potential separation of the conjunctiva from the underlying layer. This damage and bulging also prevents precise repositioning of the eye-fixation device due to the tissue displacement. L'Esperance does not teach or suggest a solution to this problem, much less using the crisscrossed channels of the present invention – in fact L'Esperance does not even discuss the problem.

Hellenkamp does not suggest any solution either – in fact, Hellenkamp discloses a device with precisely the negative features that the present invention explicitly solves. Hellenkamp teaches a hollow annular vacuum ring (annular vault) which sucks the corneal surface/conjunctiva into the ring. This displacement of the cornea into the hollow annular vacuum is retained when vacuum is broken, creating a raised circular ring in the tissue. Minor repositioning of the vacuum ring is not possible because the hollow vacuum ring tends to slip back over the ridge to reposition itself in the same location as before. The inherent nature of the device and methods taught in Hellenkamp actually prevent precise repositioning, and Hellenkamp does not even acknowledge the problem much less suggest a solution. Additionally, this displacement of the cornea into the vacuum ring causes micro-trauma on the conjunctiva which is avoided by the present invention because there is no

annular vault to allow displacement of the conjunctiva (the surface is contoured to the corneal surface between the vacuum channels).

The Commissioner in his rejection noted the importance of precise positioning of the corneal flap, but this misses the point. The damage caused to the corneal surface by prior art methods such as Hellenkamp and L'Esperance prevent repositioning in the event of poor concentration or need to adjust X-Y orientation. Therefore, although the desirability of adjustment is obvious, the means to accomplish readjustment are not when looking at the prior art. The multiple channels of the present invention hold the eye glove conjunctiva attached to the sclera taught between them, so that the conjunctiva is held flat and not separated from the sclera. This is what permits the device to realigned precisely without damage to the cornea, and this is what creates a new method of doing so. The conjunctiva is pulled to contact a surface, rather than simply sucked into a cavity.

Hellenkamp and L'Esperance demonstrate another problem in the prior art addressed by the present invention. Both Hellenkamp and L'Esperance teach vacuum rings with annular vaults to distribute vacuum. These annular vaults create high profiles requiring the use of lid specula causing greater discomfort for patients. The use of crisscrossed grooves eliminates the need for annular vaults thereby creating a lower profile device. This lower profile eliminates the need for a lid speculum in most cases, and is more comfortable for patients, especially those with narrow or tight lid openings.

Further, the more evenly distributed vacuum of the present invention, and lack of a displacement cavity, significantly reduces elevation of intraocular pressure, making procedures safer, more comfortable, and improving accuracy in femtosecond procedures. It decreases trauma to the ocular surface and conjunctiva. It is easier to reposition on the ocular globe if the initial ring position is incorrect. More precise X- and Y-adjustment of the attachment ring allows for superior concentration properties. The fixation screw is superior to prior art pincer-type fixation means. Smoother docking is possible, and less manual dexterity is required. All of these distinctions and advantages of the present invention are supported in the specification. See Specification p. 4, II. 11-21; pp. 6-7, II. 17-3; p. 11, II. 12-19.

The present invention specifically addresses the limitations of apparatus and methods such as L'Esperance and Hellenkamp. See Specification pp. 1-2, II. 15-2. It is important to note that ophthalmic surgery is an art where seemingly minor changes have significant impact.

Moreover, as shown above, Hellenkamp teaches away from the claimed invention. A prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH, 45 USPQ2d 1977 (Fed. Cir. 1998). "Teaching away" is a pointed and probative form of skepticism expressed in the prior art. Id. Teaching

away from the prior art supports a conclusion of nonobviousness. The Dow Chemical Co. v. U.S., 18 USPQ2d 1657 (Cl. Ct. 1990).

Hellenkamp teaches a “suction enhancement member.” This enhancement member acts as a diffuser and filter within the hollow ring, but does not prevent corneal displacement into the vacuum ring, which is an objective of the present invention. See Specification p. 4, ll. 14-18. The enhancement member is specifically designed to not make contact with the corneal surface in order to prevent occlusion of the vacuum ports, whereas the present invention requires surface contact to prevent corneal displacement. See Specification p. 4, ll. 1-21.

B. Claims 2 and 13.

Dependent Claims 2 and 13 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Curtin. Traversal with respect to L'Esperance or Hellenkamp is reasserted regarding independent claims 1 and 11 and further with regard to their combination with Curtin. Curtin teaches use of a “circumcorneal suction ring 122 which is a conventional device... an annular, hollow ring 124 which has an open bottom side that is applied to the surface of the eyeball around the cornea.” Curtin, col.5, ll. 46-51. As discussed above, nothing in Hellenkamp, L'Esperance, or Curtin teaches the use of crisscrossed vacuum channels as in the present invention. See Specification pp. 6-7, ll. 9-3. Nor does the rigidly fixed vacuum tube/positioning arm disclosed in Curtin teach or suggest positioning arms that permit an eye fixation apparatus to be adjusted to the eyeball as disclosed in the present

invention, as opposed to adjusting the eyeball to the apparatus, as in Curtin. See Specification p. 4, ll. 18-19; p. 7, ll. 1-3 & 18-21; p. 11, ll. 8-19.

The single rigid adjustment arm taught in Curtin provides limited position control for a conventional suction ring, and rigidly fixes the eyeball in space to rigidly align with a fixed apparatus. The adjustment arms of the present invention allow adjustment of the surgical attachment device while in contact with the eyeball, independently of any fixed external equipment – i.e. they permit adjustment of the apparatus to the eyeball, not the eyeball to the apparatus, as taught in Curtin, thereby permitting more precise adjustment. See Specification p. 4, ll. 18-19; p. 7, ll. 1-3 & 18-21; p. 11, ll. 8-19. Neither Curtin, nor L'Esperance or Hellenkamp, individually or in combination, address this problem nor suggest the solution provided by the present invention. A person of skill in the art would not see the combination of Curtin with L'Esperance and/or Hellenkamp as teaching the present invention.

C. Claims 3-10 and 14-21

Dependent Claims 3 through 10 and 14 through 21 were rejected under § 103(a) as unpatentable over L'Esperance or Hellenkamp in combination with Clark et al. Traversal with respect to L'Esperance or Hellenkamp is reasserted regarding independent claims 1, 11 and 12, and further with regard to their combination with Clark et al. The cited references simply do not disclose the elements of the present invention. In fact, Clark is not even analogous art to the present invention. Whether a cited reference is relevant art, or "analogous", is a fact based question relying on two criteria: (1) whether the art is from the same

field of endeavor, regardless of the problem addressed, and (2) if the art is not within the same field of endeavor, whether it is still reasonably pertinent to the particular problem to be solved. Wang Labs., Inc. v. Toshiba Corp., 993 F. 2d 858, 26 U.S.P.Q. 2d 1767, 1773 (Fed. Cir. 1993).

Clark does not teach an apparatus or method for adjusting the X-Y adjustment of an eye fixation device or surgical device in relation to a patient's eyeball. See Specification p. 4, II. 6-10 & 19-22; pp. 8-10, II. 3-10. Clark merely teaches an apparatus and method to perform a *bench alignment* of a keratome blade to the proper cutting depth using a microscope-like micrometer device, but Clark does not in any way address adjustment of a surgical instrument during actual surgery. The keratome blade assembly in Clark is removed from the surgical apparatus and mounted on a microscope micrometer device for calibration and setting. The entire process described in Clark occurs away from the patient and does not involve contact with the eyeball. By contrast, the present invention addresses the problem of aligning ophthalmic surgical devices *on the eyeball during surgery*, a wholly different procedure from a bench alignment. See Specification p. 11, II. 8-19. Likewise, the addition of docking screws to translation guide members in the present invention is not taught nor suggested in the Commissioner's references at all, because those references do not teach the attachment of surgical devices to an eye fixation apparatus to adjust the surgical devices to the eyeball. See Specification pp. 10-11, II. 19-2.

Based on the above, the combination of L'Esperance or Hellenkamp with Clark et al does not disclose each element of the inventions described in claims 3

through 10 and 14 through 21, nor do the references teach or suggest modification to achieve the present invention. Furthermore, Clark is not analogous art, so even if all elements were present in the three cited references, a person of ordinary skill would not look to Clark to combine with L'Esperance or Hellenkamp to achieve the present invention. Applicant therefore respectfully traverses the rejection of claims 3 through 10 and 14 through 21 based on L'Esperance or Hellenkamp in combination with Clark et al.

D. Claims 3-10

Dependent Claims 3 through 10 were rejected under § 103(a) as unpatentable over L'Esperance, Hellenkamp, and Curtin in combination with Clark et al. Traversal with respect to L'Esperance or Hellenkamp and Curtin is reasserted regarding claims 1 through 10, and further with regard to their combination with Clark et al. The cited references simply do not disclose the elements of the present invention. Clark does not in any way teach employing X- and Y-axis adjustment mechanisms on eye fixation devices, as discussed above. Clark teaches only bench alignment of cutting devices, which devices are then used in ophthalmic surgery. The rigid vacuum arm taught in Curtin does not disclose, suggest, nor teach adjustment arms permitting adjustment of the eye fixation device to the eyeball, as opposed to adjusting the eyeball rigidly to the device.

The rejections are respectfully traversed as to all claims. It is requested that the rejections be withdrawn.

CONCLUSION

For the foregoing reasons, reconsideration and allowance of Claims 1 through 21 of the application as amended is solicited. The Commissioner is encouraged to telephone the undersigned at (360) 750-9931 if it appears that an interview would be helpful in advancing the case. The Applicant respectfully submits that the rejection of the pending claims must be withdrawn, and that this application is in condition for allowance. Such is earnestly requested.

Respectfully submitted,

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